

Rotigotine

Traffic light classification- Amber 2 Information sheet for Primary Care Prescribers

CLINICAL INFORMATION

Key points/interactions

- Nausea is a common early side effect but usually responds to domperidone (10mg tds or lowest effective dose – see [MHRA advice](#))
- Rotigotine patches should be applied to a different site every day for 14 days.
- Dopamine agonists may cause compulsive/addictive behaviours such as gambling, compulsive shopping and hyper sexuality. Patients rarely recognise such changes as side effects and rarely report them unless specifically asked.

Licensed Indications

Treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. without levodopa) or in combination with levodopa, i.e. throughout the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or 'on-off' fluctuations).

Therapeutic Summary

As per the licensed indication.

NICE recommendations for the use of rotigotine in Parkinson's disease (PD) are:

- Consider a choice of dopamine agonists, levodopa or monoamine oxidase B (MAO-B) inhibitors for people in the early stages of Parkinson's disease whose motor symptoms do not impact their quality of life. Do not offer ergot-derived dopamine agonists as first-line treatment for Parkinson's disease.
- Offer a choice of dopamine agonists, MAO-B inhibitors or catechol-O-methyltransferase (COMT) inhibitors as an adjunct to levodopa for people with Parkinson's disease who have developed dyskinesia or motor fluctuations despite optimal levodopa therapy, after discussing:
 - the person's clinical circumstances, for example, their Parkinson's disease symptoms, comorbidities and risks from polypharmacy
 - the person's lifestyle circumstances, preferences, needs and goals
 - the potential benefits and harms of the different drug classes
- Choose a non-ergot-derived dopamine agonist in most cases, because of the monitoring that is needed with ergot-derived dopamine agonists. Only consider an ergot-derived dopamine agonist as an adjunct to levodopa for people with Parkinson's disease:
 - who have developed dyskinesia or motor fluctuations despite optimal levodopa therapy **and**
 - whose symptoms are not adequately controlled with a non-ergot-derived dopamine agonist.
- When treating nocturnal akinesia, consider rotigotine if levodopa and/or oral dopamine agonists are not effective

Medicines Initiation

Consultant neurologist/specialist experienced in the management of PD.

Dose Regimen

In early-stage Parkinson's disease:

- 2mg/24h as a single daily dose and then increased in weekly increments of 2mg/24h to an effective dose up to a maximum dose of 8mg/24h. 8mg/24h is usually a therapeutic dose.

In advanced-stage Parkinson's disease:

- 4mg/24h as a single daily dose and then increased in weekly increments of 2mg/24h to an effective dose up to a maximum dose of 16mg/24h
- Beyond doses of 8mg, two patches must be applied each day [and each left on for 24 hours].

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Patches should be applied to clean, dry, intact healthy skin, at approximately the same time every day. Patches must be applied to a different site each day. Reapplication to the same site within 14 days should be avoided.

Duration of treatment

Rotigotine is a treatment for chronic disease and therefore course length can be many years.

Contraindications

- Hypersensitivity to rotigotine or any of the excipients
- Remove the patch before MRI / cardioversion
- Pregnancy & breastfeeding

Precautions

- Severe hepatic impairment
- Ophthalmological testing recommended (risk of visual disorders)- see monitoring requirements
- Avoid exposure of patch to heat
- History of dementia, confusion or hallucinations – increased risk of neuropsychiatric side effects.
- If treatment discontinuation is required, this should be done gradually. The daily dose should be reduced in steps of 2mg/24h with a dose reduction preferably every other day.

Monitoring

- Ask about gambling and other addictive behaviours. Patients may deny such symptoms when first asked about them.
- Ophthalmological testing recommended (risk of visual disorders)
- Blood pressure monitoring recommended, especially at the beginning of treatment.

Adverse Effects

Side Effects	Action
Abdominal pain, dyspepsia, constipation, dry mouth	Usually transient. If persists discuss with neurologist/PD nurse specialist (PDNS)
Nausea & vomiting	Usually transient but may be quite severe. Unless very minor, prescribe Domperidone 10mg TDS (or lowest effective dose- see MHRA) during dose titration; this can usually be stopped within a few weeks.
Sedation	Usually transient. Advise patients not to drive/operate machinery if affected. If persists discuss with a neurologist.
Orthostatic hypotension	Usually transient. If persists discuss with neurologist/PDNS.
Light-headedness, dizziness, headache	Usually transient. If persists discuss with neurologist/PDNS
Palpitations, AF, SVT	Discuss with neurologist/PDNS
Leg oedema	Rarely a major problem. Discuss with a neurologist if no other explanation identified
Hallucinations, confusion	Discuss with neurologist/PDNS
Psychotic reactions (other than hallucinations), including delusion, paranoia, delirium.	Discuss with neurologist/PDNS
'Dopamine dysregulation syndrome' - manifests as a change in behaviour, typically with an obsessional, risk-taking, sexual or financial axis.	Discuss with neurologist/PDNS
Hypersensitivity reactions including urticaria, rash, angioedema.	Discontinue and discuss with neurologist/PDNS
Visual disorders	Ophthalmological testing. Discuss with neurologist/PDNS
Raised hepatic enzymes	Discuss with neurologist/PDNS
Skin reactions	Ensure rotating application site. If troublesome may need to change to an alternative agonist. Discuss with neurologist/PDNS
Erectile Dysfunction	Rarely a problem. Discuss with neurologist/PDNS

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Clinically relevant medicine interactions and their management

Patients selected for treatment with Rotigotine are almost certain to be taking concomitant medications for their Parkinson's disease. In the initial stages of Rotigotine therapy, the patient should be monitored for unusual side-effects or signs of potentiation of effect.

- **Neuroleptic medicinal products and other centrally acting dopamine antagonists** e.g. sulpiride, metoclopramide - may have an antagonistic effect if used with rotigotine. Avoid concomitant use.
- **Antihypertensives**– increased hypotensive effect
- **Memantine** - enhanced effect on dopaminergic.

For further information on contraindications, precautions, adverse effects and interactions refer to the BNF or [Summary of Product Characteristics](#).

Information given to the patient

Patients (and their family members and carers) should be given information on the following:

- The risk of excessive daytime sleepiness and sudden onset of sleep and the need to exercise caution when driving or operating machinery. If affected patients should refrain from driving or operating machinery until these effects have stopped occurring.
- The increased risk of developing impulse control disorders and related disorders including dopamine dysregulation syndrome when taking dopamine agonist therapy and that these may be concealed by the person affected. Advice should be given about who to contact if impulse control disorders develop.
- The risk of psychotic symptoms (hallucinations and delusions) with all Parkinson's disease treatments (and the higher risk with dopamine agonists).

Products available

Neupro® 1mg, 2mg, 3mg, 4mg, 6mg, 8mg patches

An estimate of the potential medicine costs (and any additional costs) to primary care

Neupro 4mg patch £123.60 (28 days)

Neupro 8mg patch £149.93 (28 days)

REFERENCES

British National Formulary. Rotigotine via NICE. [Accessed 31/03/2021].

Summary of Product Characteristics. [Neupro UCB Pharma Ltd](#). Last updated 01 Feb 2021. [Accessed 31/03/2021].

NICE NG71 Parkinson's disease in adults, July 2017. [Accessed 31/03/2021].

MHRA Drug Safety Update: Domperidone: risks of cardiac side effects, [May 2014](#)

Version Control- Rotigotine			
Version	Author(s)	Date	Changes
2.1	Shary Walker – Specialist Interface and Formulary Pharmacist	22/04/2021	– price and link updates – added version control and minor format alterations